ANIMAL HEALTH INSTITUTE

Representing manufacturers of animal health products

Alexander S. Mathews
President & CEO

November 3, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 99D-4070 – International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance on "Quality of Biotechnological products in the Veterinary Field: Stability Testing of Biotechnological/Biological Products" (VICH GL17)

The ANIMAL HEALTH INSTITUTE ("AHI") submits these comments in response to the Notice requesting comments published by the Food and Drug Administration in the *Federal Register* on Tuesday, October 12, 1999, regarding the Draft Guidance on "Quality of Biotechnological products in the Veterinary Field: Stability Testing of Biotechnological/Biological Products."

AHI is the national trade association representing manufacturers of animal health products – the pharmaceuticals, vaccines and feed additives used in modern food production, and the medicines that keep livestock and pets healthy.

The Food and Drug Administration should be applauded for embracing the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) process and entering into harmonization discussions with other regulatory authorities.

AHI has been actively involved in the VICH process, and has already had significant input into the VICH GL17 document released by the VICH Steering Committee in May 1999 for consultation at Step 4 of the VICH process. AHI has no suggestions for improving this guidance and encourages adoption by CVM.

Sincerely,

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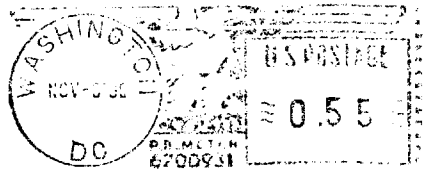

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